

CONSENT FORM

TITLE OF RESEARCH: Race, Natriuretic Peptides and Physiological Perturbations

IRB PROTOCOL NO.: IRB-170214001

INVESTIGATOR: Dr. Pankaj Arora, MD, FAHA

SPONSOR: National Institute of Health (NIH)
American Heart Association (AHA)

Purpose of the Research

We are asking you to take part in a research study.

We are asking you to join because you are a healthy subject between the ages of 18-40 who has no history of cardiovascular disease, high blood pressure or diabetes or taking any medications for any of these conditions. The purpose of this study is to understand the difference in response to medications between healthy African Americans and healthy Caucasians. In addition, exercise increases natriuretic peptide (NP) levels. We will also compare the NP levels after exercise in African-American and Caucasians.

NPs are hormones produced by the heart to in response to stress on heart walls. NP levels are used to diagnose heart failure. African-Americans have lower NP levels as compared to Caucasians. This might contribute to increased rate of heart failure and death in African Americans. Beta-blocker therapy increases NP levels which benefits heart failure patients. But beta-blockers are less effective in African Americans compared to Caucasians in heart failure treatment. NP's role in healthy individuals is not known.

We expect to enroll 40 healthy African Americans and 40 healthy Caucasians for this study at University of Alabama at Birmingham.

Explanation of Procedures

This study will take place at following locations-

- UAB Clinical Research Unit (CRU), located on 15th floor in Jefferson tower building (625 19th Street South)
- Physical Activity core (PAC), located on 2nd floor in the Webb-Mott Nutrition Science Building (1675 University Blvd.)
- Outreach laboratory, located on 2nd floor in Spain Wallace building (620 19th Street South)
- UAB Wallace Tumor Institute (WTI), PET/MR imaging suite, located in the basement of the Wallace Tumor Institute

Study Visit #1 (Screening Visit):

You will be asked to come to the CRU for the screening visit. This visit will take about 2 hours. During this visit, we will get your consent and perform the following tests and procedures to see if you can take part in the main study:

- Take your blood pressure three times. If your blood pressure is more than 140/90 or systolic blood pressure less than 100, you will not be able to continue in the study.
- If your heart rate less than 60/minute, you will not be able to continue in the study.
- Complete a questionnaire about personal information, past medical history, medications and family medical history.
- Measure your height and weight.
- If you are a female able to become pregnant, we will test your urine for pregnancy. Pregnant women cannot take part in this study.
- Draw about 25 ml or 5 teaspoons of blood. We will do the following tests on your blood- NP levels, a chemistry panel (electrolytes, kidney function and glucose), complete blood count, and a liver function panel.
- Schedule you to meet with a study nutritionist who will ask you about your dietary choices and practices.
- Give you a food log to take home and write down what you eat and drink for the next few days.

The study doctor will review the results of these blood tests and tell you if you can be in the study or not. If you cannot join the study, the study doctor will tell you the reason as well. We will suggest follow-up with your primary care physician if this is the case.

If you can join the study and decide to continue in the study, we will ask for your convenient date and time, and schedule you for visits #2 and #3.

Prior to Study Visit #2

You will fast overnight (>6 hours) prior to this visit, and will be required not to drink caffeine and alcohol beverages 24 hour prior to this visit.

Study Visit #2 (Baseline Visit/Food Pick-up)

- Visit will last about 2 hours
- You will come to the PAC for this visit. We will determine your aerobic fitness/VO2 max

- You will pick up 3 days of meals from the CRU.
- You will be provided a container for 24-hour urine collection. Urine sample will be tested for sodium, protein and creatinine levels.

We will ask you to eat a special study diet for 3 days prior to the study visit #3. The diet will include of 3 meals a day (breakfast, lunch and dinner) and snacks and will be given to you by the UAB CRU. While you are on this diet, we will ask you not to eat anything which is not given to you by the UAB CRU. In addition, we will give the meals to you at no cost. These meals will have all the nutrients required for a healthy diet.

(VO2 max stands for V - volume, O2 - oxygen, max – maximum. VO2 is the maximum amount of oxygen consumption measured during increasing exercise (for example on a treadmill). This oxygen consumption reflects the physical fitness of an individual.

(Instructions for 24-urine collection: Instruct the subject to empty bladder. Discard this specimen. Record time and date on specimen container. Collect all urine after this first voiding. Do not urinate directly into the 24-hour collection container. The specimen should be refrigerated during the collection period. The following morning (24 hours later), have the patient void, collect the urine and add this urine to the 24- hour specimen)

Prior to Study Visit #3

Three days prior to 3rd visit, you will consume the meals provided by the CRU. You will also be required to collect 24-hour urine and fast overnight (>6 hours) prior to this visit. We will also ask you not to drink alcohol and caffeine-containing beverages (such as coffee, tea, soft drinks, or energy drinks) during this time.

Study Visit #3 (Exercise Challenge Visit)

You will drop off the urine at the outreach lab or hand over to the research coordinator.

Then you will come to the PAC. This visit will last about 3 hours. When you arrive at the PAC, we will:

- Ask to lie down and rest for 30 minutes.
- Take your vitals such as blood pressure and heart rate
- Take your neck, arm, waist, hip and calf circumferences
- Measure a skinfold thickness and arterial pulse
- Perform exercise challenge test: You will wear a mask (to measure oxygen uptake and carbon dioxide production) and perform exercise. Exercise will start with a 4-minute warmup. Each subject will walk for 20 minutes and will undergo a 4-minute cool-down after the exercise.
- Measure your blood pressure for 3 times during exercise.
- Ask to rest for 30 minutes.
- Ask you to keep a mask on initial 5 minutes
- Finger stick will be performed
- Ask you to put on a mask just 5 minutes before the end of 30 minutes rest
- Draw 15cc or 3 teaspoons of blood sample 4 times (before exercise challenge,

immediately after, 15 min and 30 min later). Blood samples will be tested for natriuretic peptide levels, insulin, and glucose.

- Collect urine before and after the exercise challenge. Urine sample will be tested for sodium, protein and creatinine levels.
- Provide you a container for 24-hour urine collection

Prior to Study Visit #4

Three-seven days after 3rd visit, you will need to come for 4th visit. Prior to this visit:

- You will collect urine 24 hours prior to the visit
- You will fast overnight (>6 hours) and will not drink caffeine and alcohol beverages 24 hour prior to this visit

Study Visit #4

- Visit will take about 2 hours
- You will drop off the urine at the outreach lab. Urine sample will be tested for sodium, protein and creatinine levels.
- Then, you will come to the CRU. When you arrive at the CRU:
 - BP and heart rate (HR) will be measured and. If BP is between (140/90 - 100/50) and HR is >60 than a two-week supply of metoprolol succinate (50mg/day) will be provided.
 - If you are a female able to become pregnant, we will test your urine for pregnancy. Pregnant women cannot take part in this study.
 - You will be asked to take a rest for 1 hour
 - 20cc or 4 teaspoons of venous blood will be drawn. Blood samples will be tested for natriuretic peptide levels, insulin, glucose, renin and aldosterone.
 - You will be called by the study doctor to assess medicine side effects within 7 days after this visit

Prior to Study Visit #5

You will fast overnight (>6 hours) prior to this visit, and not to drink caffeine and alcohol beverages 24 hour prior to this visit.

Study Visit #5

- Two weeks after visit #4, you will come for this visit
- Visit will take about 2 hours
- You will come to the CRU for this visit, where we will:
 - Measure your BP and HR
 - You will be asked to take a rest for 1 hour
 - Draw 20ml or 4 teaspoons blood. Blood samples will be tested for natriuretic peptide levels, insulin, glucose, renin and aldosterone.
 - Assess compliance by doing a pill count and reviewing the calendar
 - Discuss side effects from the metoprolol use
 - Provide metoprolol succinate (100mg/day) for 2 more weeks
 - You will be called by the study doctor to assess medicine side effects

within 7 days after this visit

Prior to Study Visit #6

You will fast overnight (>6 hours) prior to this visit, and not to drink caffeine and alcohol beverages 24 hour prior to this visit.

Study Visit #6

- Two weeks after visit #5, you will come for this visit
- Visit will take about 2 hours
- You will come to the CRU for this visit, where we will:
 - Measure your BP and HR
 - You will be asked to take a rest for 1 hour
 - Draw 20ml or 4 teaspoons blood. Blood samples will be tested for natriuretic peptide levels, insulin, glucose, renin and aldosterone.
 - Assess compliance by doing a pill count and reviewing the calendar
 - Discuss side effects from the metoprolol use
 - Provide metoprolol succinate (200mg/day) for 2 more weeks
 - Provide you a container for 24 hour urine collection
 - You will be called by the study doctor to assess medicine side effects within 7 days after this visit

Study Visit #7

- Two weeks after visit #6, you will come for this visit
- Visit will take about 2 hours
- You will drop off the urine at the outreach lab. Urine sample will be tested for sodium, protein and creatinine levels.
- Then, you will come to the CRU, where we will:
 - Measure your BP and HR
 - You will be asked to take a rest for 1 hour
 - Draw 20ml or 4 teaspoons blood. Blood samples will be tested for natriuretic peptide levels, insulin, glucose, renin and aldosterone.
 - Assess compliance by doing a pill count and reviewing the calendar
 - Discuss side effects from the metoprolol use

(Modification in the study visits: At every visit, BP and HR will be measured. Metoprolol will be discontinued for any systolic BP < 80 mm Hg and HR < 40 beats/minute at visit #5 and visit #6. If you develop intolerance or any side effects from increasing the dose of metoprolol, you will go back to the maximally tolerated last dose to finish the 6-week duration.)

Study Visit #8

One week after visit #7, you will come to CRU for 8th/final visit. After 15 min of rest, BP and HR will be measured (three times) to assess your well-being. This visit will take about 2 hours. At the end of this visit, your participation will be complete.

Summary table of the study visits:

Study visit	Timing of the study visit	Location
Visit 1	Day 1	CRU
Visit 2	Within 7-10 days of visit 1	PAC and CRU (Food Pick Up)
Visit 3	4 days after visit 3	PAC
Visit 4	Within 3-7 days after visit 3	CRU
Visit 5	2 weeks after visit 4	CRU
Visit 6	2 weeks after visit 5	CRU
Visit 7	2 weeks after visit 6	CRU
Visit 8	1 week after visit 7	CRU

Risks and Discomforts

Potential breach of confidentiality

There is a slight risk that your private health information may be seen by others. But, safety measures will be taken to reduce such a problem.

Risks of Blood Draw

You may have a small amount of bleeding or a bruise may develop. Sometimes, a person feels faint or lightheaded when his/her blood is drawn. Rarely an infection can develop; it can be treated. Risk is lowered by keeping skilled person for blood draw.

Risks of Fasting

For the study, you will be asked to fast (no food to eat) for more than 6 hours overnight. Long hours of fasting cause hypovolemia (a decreased volume of circulating blood in the body) and can make you dizzy, faint, or irritable.

Risk in Food Preparation

There is a small risk that food may be not be prepared right. People who consume food that is not prepared right may experience nausea, vomiting, or diarrhea. However, the CRU metabolic kitchen follows correct policies and procedures to ensure food safety.

Risks of Metoprolol

Cardiovascular (low heart rate, cold extremities, heart failure, hypotension); dermatologic (pruritus, rash); gastrointestinal (constipation, diarrhea, indigestion, nausea); neurologic (dizziness, fatigue, headache); psychiatric (depression); respiratory (dyspnea, wheezing, bronchospasm).

Risk of driving and operating equipment during metoprolol period

Metoprolol may cause drowsiness, fatigue, dizziness or lightheadedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Risks of Caffeine Withdrawal

There is a small risk that people who take caffeine regularly, may show withdrawal symptoms like headache, fatigue or drowsiness, depressed mood or irritability, difficulty concentrating, and flulike symptoms such as nausea or muscle pain.

Risks of Alcohol Withdrawal

There is a small risk of alcohol withdrawal in people who take alcohol regularly. They may show mild symptoms such as sleep disturbances and anxiety to severe and life-threatening symptoms such as delirium, hallucinations, and autonomic instability.

Risks of Exercise

Risk of exercising include strains and tears, inflammation, stress fractures, tendonitis, heart problems such as arrhythmias, sudden cardiac arrest, and heart attack. People who do not exercise on a regular basis are more likely to suffer injuries when engaging in such activity.

Benefits

You will not benefit from taking part in this study. The results of this research study may help us understand different racial response to cardiovascular risk.

Alternatives

Your alternative is to not participate in this research study.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, Department of Medicine, Division of Cardiology, the Office for Human Research Protections (OHRP) and the study sponsor, NIH and AHA. The information from the research may be published for scientific purposes; however, your identity will not be given out.

If any part of this study takes place at University of Alabama Hospital this consent document will be placed in your file at that facility. The document will become part of your medical record chart.

Information relating to this study, including your name, medical record number, date of birth and social security number, may be shared with the billing offices of UAB and UAB Health System affiliated entities so that the costs for clinical services can be appropriately paid for by either the study account or by the patient/patient's insurance.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study.

Payment for Participation in Research

You will receive \$25 for screening visit, \$50 for 2nd, 3rd, 4th, 5th, 6th and 7th visits (each visit), and \$25 for 8th/final visit in about 4 weeks after study visit. This will be a total of \$350. Ask the study staff about the method of payment that will be used for this study (e.g., check, direct deposit).

Payment for Research-Related Injuries

UAB and the study sponsors, NIH and AHA have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings

You will be told by your doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Optional Research

Please note: This section of the consent form is about optional research that is being done with people who are taking part in this study. You may take part in this optional research if you want to. You can still be a part of this study even if you say no to take part in any of the optional research.

You can say "yes" or "no" to each of the following studies. Please mark your choice for each study.

Future Contact

We would like your permission to contact you about being in future research projects related cardiovascular and metabolic diseases. Based upon result of this visit and test results, we may contact you by phone or in writing about future studies. You can say no to participate in these studies.

_____ I agree to allow you to contact me about other studies

_____ I DO NOT agree to allow you to contact me about other studies

Genetic Testing

We would like to request your permission to collect ½ tablespoon of whole blood to extract DNA and store that for future studies. We are not going analyze your DNA study information for this protocol. The DNA that composes of your genes will be analyzed and that data, which is referred to your genotype or complete genetic makeup, compared to your phenotype, which consists of your observable traits, characteristics, and diseases in the future.

There are multiple genes involved in the regulation of human blood pressure. Until recently, no common genetic variants had been found which were related to human blood pressure. A genetic variant is a change in a particular gene that may affect the health of the person who has it. Recently, researchers have discovered a genetic variant which is present in about 1 out of 10 people and is related to blood pressure and to levels of natriuretic peptides.

We may pursue to study these genetic variates in the future. The future research related to these genetic variates may be conducted by Dr. Pankaj Arora or other researchers after the IRB's approval for their research. How your identity relates to these specimens will be coded and only Dr. Pankaj Arora will have access to it.

The results related to these future studies will not be disclosed to you or your doctor.
Initial your choice below:

_____ I agree to allow you to store DNA to test for genetic variants.

_____ I DO NOT agree to allow you to store DNA you to test for genetic variants.

Gene Expression

We would like to request your permission to collect ½ teaspoon of whole blood in special tube called PAXgene to extract RNA and store that for the current study during each time-point. Through RNA extraction, we are going to see gene expression of certain natriuretic peptide family of genes in whole blood. The principal role of RNA is to act as a messenger carrying instructions from DNA for controlling the synthesis of proteins.

Do you agree to let us store RNA from your blood and contact you for the future studies related to genetic variants?

Initial your choice below:

_____ I agree to allow you to store RNA to test for its expression in the current study.

_____ I DO NOT agree to allow you to store RNA to test for its expression in the current study.

Positron Emission Tomography and Magnetic Resonance Imaging

Positron emission tomography (PET) is a type of imaging test that uses a small amount of radioactive material injected into your vein to see how cells or tissues are functioning. It is combined with a Magnetic Resonance Imaging (MRI) (a test that uses magnetic fields and radio waves to generate images of the inside of your body) in one machine so doctors can better see the structures the PET agent goes to. Before the scan, you will have to follow preparation instructions including not eating for 6 hours before the test. After the PET agent is injected, you will wait 45-60 minutes before being scanned. The scan will take 20 minutes, and you must lie still during that time.

In this study you will have a MRI exam. A magnetic resonance imaging (MRI) exam is a test that uses magnetic fields and radio waves to generate images of the inside of your body.

You will be placed inside a scanner and asked to lie still for about 20 minutes. This is a noisy exam; you will be given earplugs to protect your hearing.

We are performing imaging solely for the research purposes described above. It is not a clinical scan intended for diagnostic or therapeutic purposes. Under no circumstance will the investigator, research staff, or imaging staff interpret the scan as normal or abnormal. They are unable to make any medical comments about your scan. The scan will not be looked at or read for any healthcare treatment or diagnostic purpose. If you want your scan to be reviewed by a physician so the physician can look for medical issues, you can request a copy of your scan. We will provide an electronic copy at no charge.

There will be no cost to you for taking part in this optional research. The NIH is funding this study and will cover the cost of the study.

Risks of Positron Emission Tomography (PET)

Because the doses of radiotracer administered are small, diagnostic nuclear medicine procedures result in low radiation exposure, acceptable for diagnostic exams. Thus, the radiation risk is very low compared with the potential benefits. Nuclear medicine diagnostic procedures have been used for more than five decades, and there are no known long-term adverse effects from such low-dose exposure. Allergic reactions to radiopharmaceuticals may occur but are extremely rare and are usually mild. Nevertheless, you should inform the nuclear medicine personnel of any allergies you may have or other problems that may have occurred during a previous nuclear medicine exam. Injection of the radiotracer may cause slight pain and redness which should rapidly resolve. Women should always inform their physician or radiology technologist if there is any possibility that they are pregnant or if they are breastfeeding their baby.

In this study, you will be exposed to some radiation from the PET scans. The radiation from the each scan is approximately equal to 2 years of exposure to natural background radiation. Background radiation is radiation normally received from sources such as cosmic rays and natural radioactivity in building materials and the ground. There is a small risk that the radiation may cause cancer or other radiation effects in several years.

Risks of Magnetic Resonance Imaging (MRI)

MRI uses a strong magnetic field and non-ionizing radiofrequency pulses to generate images of the human body. These images will provide information about the type and relative amount of a particular tissue present in participant’s body. In this study, we are particularly focused on the neck, shoulders and chest MRI has negligible risks for most people; however, if you have any metal objects in your body MRI may not be safe for you and you will not be allowed to take part in this study.

During the exam, you will be in a small, enclosed space. If you suffer from a fear of enclosed spaces, or experience extreme anxiety during the exam, please let the research staff know immediately.

Thermal Imaging

If you agree to participate with the PET/ MRI imaging, we will take an infrared picture of your body just prior to the PET/MRI. This is a picture taken with a special camera called a thermographic or infrared camera. We are taking this picture to detect your body surface temperature. There are no additional risks involved with this noninvasive infrared picture.

Initial your choice below:

_____ I agree to participate with PET/MRI imaging.

_____ I DO NOT agree to participate with PET/MRI imaging.

If you agree to participate with PET/MRI imaging, you will come to the UAB Wallace Tumor Institute (WTI), PET/MR imaging suite, located in the basement of the Wallace Tumor Institute on visit # 4 and 7 after completing CRU visit.

Summary table of the study visits (if you agree to participate in PET/MRI imaging):

Study visit	Timing of the study visit	Location
Visit 1	Day 1	CRU
Visit 2	Within 7-10 days of visit 1	PAC and CRU (Food Pick Up)
Visit 3	4 days after visit 3	PAC
Visit 4	Within 3-7 days after visit 3 + PET/MRI imaging	CRU and WTI
Visit 5	2 weeks after visit 4	CRU
Visit 6	2 weeks after visit 5	CRU
Visit 7	2 weeks after visit 6 + PET/MRI imaging	CRU and WTI

Visit 8	1 week after visit 7	CRU
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Payment for Participation in PET/MRI imaging

You will receive an additional \$100 (\$50 for each visit) for participating in this optional study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, you may contact Dr. Nirav Patel and Dr. Pankaj Arora. They will be glad to answer any question. Dr. Patel's number is 205-934-6058 and Dr. Arora's number is 205-936-6630. Dr. Patel may also be paged after hours at 205-435-5866.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Storage of Specimens for Future Use

After we have processed your blood samples for this research study we would like to store any leftover blood at UAB for future research related to cardiovascular and metabolic disease. The future research may be conducted by Dr. Pankaj Arora or by other researchers that obtain IRB approval for their research. The specimens will be labeled with a code that only Dr. Pankaj Arora can link back to you. Results of any future research will not be given to you or your doctor. The specimens obtained from you in this research may help in the development of a future commercial product. There are no plans to provide financial compensation to you should this occur.

You do not have to agree to allow your blood specimens to be stored in order to be part of this study. You may request at any time that your research samples be removed from storage and not be used for future research. If you decide you want your samples removed, you may contact Nirav Patel at npatel@uabmc.edu or 205-934-6058 or Dr. Pankaj Arora at the University of Alabama at Birmingham at parora@uabmc.edu. Once the request is received, and if your samples have not already been used for other research, they will be destroyed. If you do not make such a request, your specimens will be stored indefinitely or until used.

Initial your choice below:

_____ I agree to allow my samples to be kept and used for future research on hypertension.

_____ I do not agree to allow my samples to be kept and used for future research.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant

Date

Signature of Person Obtaining Informed Consent

Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF
PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____
Research Protocol: **Race, Natriuretic Peptides and**
Physiological Perturbations
Peptide Response to Exercise and Beta-blockers.

UAB IRB Protocol Number: **IRB-170214001**
Principal Investigator: **Pankaj Arora, MD, FAHA**
Sponsor: **UAB Division of Cardiology, NIH, American Heart**
Association

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____

or participant's legally authorized representative: _____ Date: _____

Printed Name of participant's representative: _____

Relationship to the participant: _____